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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,300	06/15/2001	Lieven De Veylder	2364/300 (C 2681 US)	7567

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08/06/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

14

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/868,300

Applicant(s)

DE VEYLDER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-34 and 41-50 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11,12,24-34 and 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-10, 13-23 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 47-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The Amendment filed May 27, 2003, paper no.12, has been entered.

Claim 4 is newly cancelled.

Claims 1, 18, 20 and 22 are newly amended.

Claims 47-50 are newly added.

Claims 4 and 35-40 are cancelled.

Claims 1-3, 5-34 and 41-50 are pending.

Claims 2-3, 11-12, 24-34 and 41-49 are withdrawn from consideration.

Claims 1, 5-10, 13-23 and 50 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 47-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted claims 47-49 are directed to a method for using an isolated DNA molecule having the sequence set forth in SEQ ID NO:7 in marker assisted breeding, a method for detecting the DNA molecule of claim 1 in a transgenic plant, and a method for detecting in a plant an endogenous gene encoding a cell cycle interacting protein, whereas the invention previously elected for prosecution is directed to a DNA sequence encoding a cell cycle interacting protein, a vector, a host cell, a method for the production of transgenic plants, a transgenic plant and plant cell. The methods recited in newly submitted claims 47-49

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are distinct from the elected method for the production of transgenic plants in that they require different method steps and/or different method components.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 47-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed May 29, 2003, Paper No. 13, is attached to the instant Office action.

Claim Objections

Claim 1 is objected to because of the following informalities: part (a) in claim 1 (DNA molecules) does not agree in number with part (ab) in claim 1 (the nucleotide sequence as given in SEQ ID NO:7). Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1 and 5, and claims 6-10 and 13-23 dependent thereon, remain rejected, and claim 50 is rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 29, 2003.

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Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant points out that reduction to practice is only one way of showing possession of the invention, and that the written description guidelines provide for the use of other indicia to show possession. Applicant additionally points out that the claims recite that the isolated DNA molecule encodes a cell cycle-interacting protein that binds to a cyclin-dependent kinase having a PPTLARE motif, and Applicant points to page 4 as describing the relevant identifying characteristics recited in the claims. Applicant argues that the disclosure of such functional characteristics coupled with a known or disclosed correlation between function and structure are sufficient to show that applicant was in possession of the claimed invention, and that one skilled in the art would reasonably believe applicants invented the subject matter recited therein (reply pages 14-16).

Recitation in the specification and the claims that that the isolated DNA molecule encodes a cell cycle-interacting protein that binds to a cyclin-dependent kinase having a PPTLARE motif is not sufficient to describe the structure of the nucleic acid sequences that encode functional polypeptides. Such a recitation does not describe what structural features would be retained by the functional embodiments encompassed by the claims, which are directed to an enormous number of sequences exhibiting varying degrees of homology and identity to SEQ ID NOS: 7 and 8. Furthermore, while the disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure may be sufficient to show possession of the claimed invention, the Examiner maintains that Applicant has not disclosed what structural characteristics of

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SEQ ID NOS: 7 and 8 are correlated with the specific function(s) of SEQ ID NOS: 7 and 8.

Claims 1, 10 and 19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "cell cycle interacting protein", for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that the amendment of claim 1 to recite that the isolated DNA molecule encodes a cell cycle-interacting protein that binds to a cyclin-dependent kinase having a PPTLARE motif should overcome the rejection (reply page 17).

The amendment of claim 1 does not overcome the rejection because many different types of proteins may bind a cyclin-dependent kinase to produce different types of effects on the cell cycle. For example, a cyclin may bind a cyclin-dependent kinase and have a positive effect on the cell cycle, whereas a cyclin-dependent kinase inhibitor may bind a cyclin-dependent kinase and have a negative effect on the cell cycle. It remains unclear what function the protein exhibits, as the relationship between the binding of the cell cycle-interacting protein to a cyclin-dependent kinase having a PPTLARE motif and the cell cycle is unclear.

Claim 18 remains rejected, and claim 50 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "environmental stress", for the reasons of record set forth in the office action mailed January 29, 2003.

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Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that it is well known in the art that plants suffer from a limited number of abiotic stresses, and points to Exhibit A, the submitted reference of Salisbury and Ross (Chapter 26: Stress Physiology in Plant Physiology, Salisbury and Ross, 1992, Wadsworth Inc., Ca, USA, pages 575-600). Applicant also points out that a basis for the use of "environmental stress" may be found in the specification at pages 34 and 37 (reply page 18).

First, the rejected claim is not limited to abiotic stress; in this respect the Examiner notes that the specification makes reference to biotic as well as abiotic stress in the specification at page 37. Furthermore, the number of different abiotic stresses listed in the submitted reference of Salisbury and Ross is neither insignificant nor exclusive. For example, Lichtenthaler (Ann N Y Acad Sci. 1998 Jun 30;851:187-98) teaches abiotic stresses in addition to those taught by Salisbury and Ross, such as herbicides, pollutants and heavy metals (page 189 Table 1). Additionally, the types of stress recited in the specification at pages 34 and 37 are not interpreted as limiting the term "environmental stress" in the rejected claim. The Examiner maintains that the metes and bounds of the claim are unclear as it is unclear what type(s) of stress the transgenic plant cell of claim 18 would be less sensitive to.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Claim 5 remains rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that the amendment of claim 1 to recite "an isolated DNA molecule" should overcome the rejection, since claim 5 depends from claim 1 (reply pages 18-19).

The amendment of claim 1 to recite "an isolated DNA molecule" does not overcome the rejection because while claim 5 depends from claim 1, claim 5 is directed to a nucleic acid molecule that hybridizes with a DNA sequence of claim 1. Accordingly, the nucleic acid molecule of claim 5 does not incorporate the "isolated" limitation recited in claim 1. It is suggested that claim 5 be amended to recite that the nucleic acid molecule is isolated in order to obviate the rejection.

Claims 1, 5-10 and 13-23 remain rejected, and claim 50 is rejected, under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record set forth in the office action mailed January 29, 2003.

Claims 1, 5-10 and 13-23 remain rejected, and claim 50 is rejected, under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons

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set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant points to page 72 of the specification, which discloses that the claimed DNA sequence has overall perfect homology with a partial Hal3 cDNA, isolated from *Arabidopsis* and entered on the gene databank. Applicant also points to page 72 of the specification as disclosing that the *HAL 3* gene, first isolated as a halotolerance gene from *S. cerevisiae*, encodes a protein which regulates the cell cycle and salt stress tolerance. Applicant asserts that based on the homology of SEQ ID NO:8 to HAL3, the inventors teach that the claimed DNA is useful for enhancing growth and conferring salt tolerance to plants. Applicant additionally points to Exhibit B, the submitted reference of Espinosa-Ruiz et al. (1999, The Plant Journal, Vol. 20, No. 5, pages 529-539), as teaching the isolation of two *Arabidopsis* genes having homology to the *S. cerevisiae* HAL3 gene, and as teaching that transgenic plants overexpressing AtHAL3a show a faster growth rate and improved salt and osmotic tolerance. Applicant further points out that the protein of SEQ ID NO:8 is highly homologous to the AtHAL3a protein, and exhibits the same expression pattern as AtHAL3a. Applicant argues that an asserted utility based on homology to existing nucleic acids or proteins having a known utility must be accepted absent evidence or reasoning to the contrary, and Applicants argue that the high degree of homology between SEQ ID NO:8 and AtHAL3a combined with the teachings of Espinosa-Ruiz et al. demonstrating the utility of AtHAL3a are sufficient to rebut the

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rejection of the claims based on a lack of utility under 35 USC 101, as well as the rejection of the claims under 35 USC 112, first paragraph (reply pages 19-21).

The Examiner acknowledges the teaching at page 72 of the specification, which discloses that the claimed DNA sequence has overall perfect homology with a partial *Arabidopsis* Hal3 cDNA, but maintains that absent a showing that the perfect homology correlates with a region(s) known to be essential for HAL3 protein function, the overall perfect homology between SEQ ID NO:7 and the partial *Arabidopsis* Hal3 cDNA does not support a utility for SEQ ID NO:7. The Examiner also acknowledges the teaching at page 72 of the specification regarding the *S. cerevisiae* HAL3 gene and the assertion that the claimed DNA is useful for enhancing growth and conferring salt tolerance to plants, as well as the teachings of Espinosa-Ruiz et al. regarding the utility of the nucleic acid encoding AtHAL3 and Applicant's assertion that the protein of SEQ ID NO:8 is highly homologous to AtHAL3a. The Examiner maintains, however, that as the prior art teaches that general structural homology between amino acid sequences is not always predictive of functional homology, a showing that SEQ ID NO:8 exhibits specific structural homology to HAL3 in regions known to be essential for HAL3 function would be necessary in order to demonstrate a utility for SEQ ID NO:8 based on homology to HAL3. Such a showing is particularly crucial given that the specification discloses the DNA sequence of SEQ ID NO:7 as encoding a polypeptide corresponding to a partial open reading frame, as the additional amino acids corresponding to the remainder of the open reading frame could be required for protein function.

Claim Rejections - 35 USC § 102

Claims 1 and 5-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by De Veylder et al. (FEBS Letters, 1997, Vol. 412, pages 446-452), for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that the amendment of the claims to recite specific hybridization conditions should overcome the rejection as the DNA sequence taught by DeVeylder et al. would not hybridize to the claimed DNA molecules under the conditions recited (reply page 21).

The amendment of the claims to recite specific hybridization conditions does not overcome the rejection because the claims as amended are directed to DNA molecules obtainable by screening an appropriate library under the stringent conditions recited with a probe having at least 17 consecutive nucleotides of the sequence set forth in SEQ ID NO:7. The DNA sequence taught by DeVeylder et al. would be obtainable by screening an appropriate library under the stringent conditions recited with a probe having at least 17 consecutive nucleotides of the sequence set forth in SEQ ID NO:17, because the DNA sequence taught by DeVeylder et al. encodes a polypeptide that binds Cdc2bAt, as does the polypeptide of SEQ ID NO: 8. While the full length sequence taught by DeVeylder et al. may not hybridize to the full length sequence of SEQ ID NO:7 under the recited conditions, the DNA sequence taught by DeVeylder et al. would necessarily contain a region that would hybridize to at least 17 consecutive nucleotides of the sequence set forth in SEQ ID NO:7 where the at least 17 consecutive nucleotides correspond to the

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region of SEQ ID NO:7 that encodes the amino acids of SEQ ID NO:8 that mediate the binding of SEQ ID NO:8 to Cdc2bAt. Additionally, the claims continue to be directed to a nucleotide sequence encoding at least the domain binding to CDKs of the protein encoded by the nucleotide sequence of any one of (aa) to (ad). As previously asserted at page 12 of the office action mailed January 29, 2003, the DNA sequence taught by De Veylder et al. would inherently encode at least the domain binding to CDKs, as CKS proteins are known to bind to CDKs.

Claim Rejections - 35 USC § 103

Claims 1, 5-10 and 13-23 remain rejected, and claim 50 is rejected, under 35 U.S.C. 103(a) as being unpatentable over Doerner et al. (Nature, April 1996, Vol. 380, pages 520-523) in view of De Veylder et al. (FEBS Letters, 1997, Vol. 412, pages 446-452), for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed May 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that the amendment of the claims to recite specific hybridization conditions should overcome the rejection as the DNA sequence taught by DeVeylder et al. would not hybridize to the claimed DNA molecules under the conditions recited, and that absent a teaching or suggestion for an isolated DNA sequence encoding a cell cycle interacting protein which binds to a CDK having a PPTLARE cyclin binding motif wherein said DNA sequence is set forth in (aa) through (af) of claim 1, the claimed invention is not obvious (reply page 22).

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As discussed *supra* under 35 U.S.C. 102(b), the isolated DNA sequence taught by DeVeylder et al. would meet the limitations of claim 1 (ae) and (af). Accordingly, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for

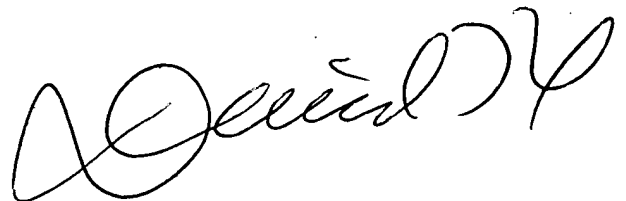
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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
July 31, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.